AF 1644 IDW

TRANSMITTAL OF APPEAL BRIEF

Docket No.
NY-LUD 5543-US3-CONT

In re Application of: Laure Dumotier

Application No.	Filing Date	Examiner	Group Art Unit
09/751,797	December 29, 2000	P. Gambel	1644

Invention: ISOLATED NUCLEIC ACID MOLECULES WHICH ENCODE T CELL INDUCIBLE FACTORS.

TO THE COMMISSIONER OF PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed: April 25, 2005 .

The fee for filing this Appeal Brief is $ 250.00 .

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[ ] A petition for extension of time is also enclosed.

The fee for the extension of time is _____ .

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[x] The Director is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-0624 .
This sheet is submitted in duplicate.

Dated: 6/22/05

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Application No. (if known): 09/751,797 Attorney Docket No.: LUD 5543.3 CONT (10027207)

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Fee Transmittal (1 page)
Appeal Brief (10 pages)
Appeal Brief Transmittal (1 page)
Appendix A - Claims
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PTO/SB/17 (12-04v2)
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Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

[x] Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 250.00

Complete if Known	
Application Number	09/751,797
Filing Date	December 29, 2000
First Named Inventor	Laure Dumotier
Examiner Name	P. Gambel
Art Unit	1644
Attorney Docket No.	LUD 5543.3-CONT (10027207)

METHOD OF PAYMENT (check all that apply)

[x] Check [ ] Credit Card [ ] Money Order [ ] None [ ] Other (please identify): _____

[ ] Deposit Account Deposit Account Number: 50-0624 Deposit Account Name: Fulbright & Jaworski L.L.P.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

[ ] Charge fee(s) indicated below
[ ] Charge fee(s) indicated below, **except for the filing fee**
[x] Charge any additional fee(s) or underpayment of fee(s) under 37 CFR 1.16 and 1.17
[x] Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fee ($)**	**Small Entity Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
_____	- =	_____	x _____	=	_____

Multiple Dependent Claims	
Fee ($)	**Fee Paid ($)**
_____	_____

Indep. Claims		**Extra Claims**	**Fee ($)**		**Fee Paid ($)**
_____	- =	_____	x _____	=	_____

3. APPLICATION SIZE FEE

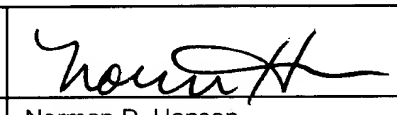
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		**Extra Sheets**		**Number of each additional 50 or fraction thereof**		**Fee ($)**		**Fee Paid ($)**
_____	- 100 =	_____	/50	_____	(round **up** to a whole number) x	_____	=	_____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): 2402 Filing a brief in support of an appeal	250.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	30,946	Telephone	(212) 318-3168
Name (Print/Type)	Norman D. Hanson			Date	6/22/05

Docket No.: LUD 5543.3 CONT (10027207)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Laure Dumoutier

Application No.: 09/751,797 — Confirmation No.: 5783

Filed: December 29, 2000 — Art Unit: 1644

For: ISOLATED NUCLEIC ACID MOLECULES WHICH ENCODE T CELL INDUCIBLE FACTORS. — Examiner: P. Gambel

APPEAL BRIEF
(37 C.F.R. § 41.37)

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants submit this Appeal Brief further to the Notice of Appeal, sent to the USPTO via facsimile on April 25, 2005.

As required under § 41.37(a), this Appeal Brief is filed within two months of the Notice of Appeal filed in this case on April 25, 2005, and is in furtherance of said Notice of Appeal.

A check in the amount of $250.00 accompanies this Brief, as required under 37 C.F.R. § 41.20(b)(2) are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

The appealed claims have been twice rejected, making the appeal proper.

This brief contains items under the following headings as required by 37 C.F.R. § 41.37 and M.P.E.P. § 1206:

I.	Real Party In Interest
II	Related Appeals and Interferences
III.	Status of Claims
IV.	Status of Amendments
V.	Summary of Claimed Subject Matter
VI.	Grounds of Rejection to be Reviewed on Appeal
VII.	Argument

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is the assignee, Ludwig Institute for Cancer Research.

II. RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

Appellants, appellants' legal representative, and assignee are collectively unaware of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect, or be directly affected by, or have a bearing on the Board's decision in this pending appeal.

III. STATUS OF CLAIMS

At present, claims 1, 3, 4, 7, 8, 10, 11, 14-16, 18, 19, and 50-56 are pending.

Claims 53-56 are allowed, and are not the subject of this appeal.*

Claims 1, 3, 4, 7, 8, 10, 11, 14-16, 18, 19, and 50-52 have been twice rejected, and are the subject of this appeal.

Claims 2, 5, 6, 9, 12, 13, 17, and 20-49 were canceled by preliminary amendment.

The claims involved in this appeal are presented in the accompanying Claims Appendix.

IV. STATUS OF AMENDMENTS

The subject application has not been finally rejected; however, the Office Action of February 10, 2005, rejected the appealed claims for the second time.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The subject matter covered by the claims on appeal are isolated nucleic acid molecules which encode a T cell inducible factor, which activates STAT3. The claims cover any nucleic acid molecules which satisfy these functions, and which have a structure that

* At page 12 of the Office Action, the Examiner states "claims 52-56 appear to be free of the prior art. Accordingly, claims 52-56 are deemed allowable." NO prior art was used to reject the claims, so it appears that all claims are free of the prior art. Further, it does not appear that the Examiner has allowed claim 52.

permits hybridization of its complement to any of SEQ ID NOS: 7, 8, 24, or 25, at specifically recited conditions.

Expression vectors employing these nucleic acid molecules are claimed as are recombinant cells containing the nucleic acid molecules, or the expression vectors.

SEQ ID NO: 7 was isolated via a process set out in example 6, over pages 11-12. It was then used as a probe to identify SEQ ID NO: 8. See Example 7. Example 8 describes another clone. It, too, hybridized to SEQ ID NO: 7. The protocol by which SEQ ID NO: 24 was isolated is presented over pages 25-26, and that of SEQ ID NO: 25, at pages 26-27.

The hybridization conditions recited in the claims are set forth at page 29, which also describes the subject matter of claim 1. Molecular weights of the preferred encoded proteins are set forth at page 29 (17-30 kilodaltons) and are found in claim 50.

VI. GROUNDS OF OBJECTION TO BE REVIEWED ON APPEAL

There appear to be two grounds of rejection.

At page 1 of the February 10, Office Action, at point 4, the Examiner has rejected claims 1, 3, 4, 7, 8, 10, 14-16, 18, 19, and 50-52 under 35 U.S.C. § 112, for allegedly failing to satisfy the enablement requirement.

At page 8 of the rejection, point 5, the Examiner rejects all of these claims, i.e., claims 1, 3, 4, 7, 8, 10, 14-16, 18, 19, and 50-52 under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the written description requirement.

VII. ARGUMENT

A. The Rejection of The Claims for Failing to Satisfy the Enablement Requirement Should Be Reversed.

The claims of a patent application are presumed to be enabled. In re Wright, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The burden rests with the Examiner to rebut this presumption. In connection with these guidelines, In re Marzocchi, 169 USPQ 367, 369 (CCPA 1971) points out that:

> "The first paragraph of § 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples, or by broad terminology, is of no importance."

Marzocchi goes on to state:

> "As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing an defining the subject matter sought to be *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt does exist, a rejection for failure to teach how to make and/or use will be proper on the basis; such a rejection can be overcome by suitable proofs indicating that the teaching contained in the specification is truth enabling."

While the Marzocchi decision is over 30 years old, it remains good law, and appellants submit that it sets forth the appropriate standard by which an argument that claims are not enabled are judged. Indeed, again with reference to Marzocchi, at 370:

> "In any event, it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement."

Appellants submit that this standard has not been met.

It is difficult to ascertain precisely why claims 1, 3, 4, 7, 8, 10, 11, 14-16, 18, 19 and 50-52 ("the claims" hereafter) have been deemed to lack enablement. The Examiner appears to be alleging that, because a number of different molecules would hybridize to the reference nucleotide sequences, but would not stimulate STAT3, or, because there are a number of molecules which encode proteins that stimulate STAT3, but do not hybridize to the reference nucleotide sequence, the claims are not enabled. The Examiner has graciously repeated his former rejection in the new Office Action, but as noted supra, the rejection fails to overcome the presumption of enablement.

The Examiner is reminded that the claims require that the nucleic acid molecules embraced thereby both hybridize to reference nucleotide sequences, and stimulate STAT3. To this end, appellants have requested the Examiner to provide evidence of any molecule that hybridizes to the reference nucleotide sequences, but does not stimulate STAT3.

No such evidence has been provided. Dumoutier and Ebert both describe molecules which do satisfy these requirements. The Examiner concedes this, at page 2 of the Office

Action of February 10, 2005. How, then, can these references support a *prima facie* case of lack of enablement?

The Examiner's position appears to be, however, that notwithstanding the law, appellants can only claims specifically disclosed sequences:

> "If appellant is asking whether the enablement references disclose or do not disclose molecules other than SEQ ID NOS: 7, 8, 24, and 25 have the same properties as these references sequences, the answer if no."
>
> For that matter, neither has appellant. Applicants has not provided for those nucleic acids that encode 'isolated nucleic acids which encodes (sic; encode) a T cell inducible factor which is a protein and activates STAT3' other than the referenced SEQ ID NOS: 7, 8, 24, and 25."

(Office Action of February 10, 2005, page 2).

Appellants do NOT have to provide details of every species that falls within the claims. All they need do is show the art how to do what they claim in order to satisfy the enablement requirement. See, e.g., Johns Hopkins University v. Cellpro, Inc., 152F.3d 1342, 1361 (Fed. Cir. 1998); Engel Industries v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991), expressly holding that there is no requirement that the specification enable every mode for making and using claimed products. As the Examiner concedes that appellants have done this, and concedes that Dumoutier and Ebert are not to the contrary, one then has to look to the remainder of the Examiner's case for non-enablement.

As Dumoutier and Ebert do not support the rejection, the Examiner's case then boils down to non-prior art Skolnick, which as pointed out, during prosecution warns of the dangers in drawing conclusions based solely on homology from computer data bases.

The subject application, however, provides more than this. Assuming that a nucleic acid molecule does hybridize as claimed - and appellants show how to determine this - then one determines whether the encoded protein activates STAT3. Again, the specification shows how to determine this.

Indeed, Skolnick counsels the art to test proteins, rather than just rely on homology. Appellants have done the same thing, and include a functional requirement in the claims. Hence, Skolnick does not support the Examiner's position either.

It is submitted that the Examiner has not rebutted the presumption of enablement that any application, and any claim, is entitled to. As the Examiner has failed to carry the

requisite burden, it is submitted that the rejection of the claims as not being enabled cannot be sustained, and should be reversed.

The Written Description Rejection

The Examiner has set forth a written description requirement rejection, beginning at page 8, point 5 of the February 8, 2005 Office Action. It is believed this rejection is in error, and should be reversed.

It is submitted that the rationale for the rejection begins incorrectly, and proceeds downhill. Page 8 contains the following statement:

> "For example, the specification discloses a diversity of structure and function of the disclosed T cell inducible factors encoded by nucleic acid molecules consisting of SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 24 and SEQ ID NO: 25."

Literally, this is true, as will be the case for any claim covering more than a single molecule; however, it is an incomplete statement of what the specification shows what the application claims and what the applicable law requires.

Appellants agree that there is diversity in the structure of the claimed molecules. They also agree that the molecules claimed have diverse properties; however, what is relevant is:

(a) They all have complements which hybridize to reference sequences, at specific conditions, all of which are recited in the claims;

(b) They all encode proteins which stimulate STAT3, which is also recited in the claims.

How these features, i.e., the "diversity of structure and function" impact written description is not clear. It is noted that claims 53-56, which also cover molecules of diverse structure and function, were allowed. The only difference is that claims 53-56 require specific sequences while the claims that have been rejected do not.

It would thus appear that the Examiner is taking the position that a claim which does not require a specific nucleotide sequence, is not adequately described. No precedent supports this point of view.

The Examiner goes on to rely on four cases, none of which are particularly relevant as has been pointed out during prosecution, several times.

First, the Examiner cites to Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991) allegedly for the proposition that "applicant must convey with reasonable clarity to these skilled in the art that, as of the filing date, he or she was in possession of the invention."

Appellants agree that this is the correct standard. They also point out that they have not asked for a priority date earlier than that on which they first set forth the language of the claims, nor has the Examiner challenged priority.

This is important because the facts in Vas-Cath are manifestly different that those presented here.

In Vas-Cath, the question at issue was whether a design application, which of course presented only drawings, supported a later filed, utility application, which presented claims that included elements which did not necessarily flow, inherently, from the design application. The Federal Circuit felt that this issue had not been resolved, and reversed and remanded for further prosecution.

As was pointed out, supra, this case does not rise or fall on whether a priority claim can be satisfied. Appellants agree that if their application does not adequately describe the claimed invention as of its filing date, this cannot be corrected.

The Examiner next turns to Fiers v. Revel, 25 USPQ2d 1601 (Fed. Cir. 1993), alleging that:

> "Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required."

Fiers at 1606; however, Fiers goes on to point out that Revel never had a single nucleic acid molecule in his possession. See Fiers at 1603.

Further, the Fiers case involved an interference where the Count read:

> "A DNA which consist essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide."

No hybridization language was included, and as the Federal Circuit pointed out:

> "Because the count at issue purports to cover all DNAs that code for β-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112."

As compared to the present case, Fiers' specification was indeed woefully inadequate. Fiers described NO nucleotide sequences. Appellants describe four. Further, in contrast to

Fiers, appellants are not claiming all molecules which satisfy the function of encoding cell inducible factors and activating STAT3. The molecules must also possess complements which hybridize as described in the claims.

Later cases, and the USPTO's own guidelines, discussed infra, show that Fiers is not pertinent when a disclosure is as complete as appellants.

Nor does Amgen Inc. v. Chugai Pharmaceutical, Co., 18 USPQ2d 1016 (Fed. Cir. 1991), support the Examiner's position.

Indeed, Amgen points to Utter v. Hiraga, 6 USPQ2d 1714 (Fed. Cir. 1988), holding that a specification may provide adequate written description of a broad claimed invention without describing all species. As with Fiers, Amgen sought to claim all EPO gene analogues. The claim at issue, i.e.:

> 7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.

is much broader than the claim at issue here.

Reliance on University of California v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed. Cir. 1997), is also misplaced, because again, the facts in this case indicate that there were no nucleotide sequences presented to support a broad, generic claim, which did not contain structural limitations such as the hybridization language of the present claims. Further, the USPTO's own, Interim Written Description Guidelines draw clear, unequivocal distinctions between the type of claims at issue in the cases cited by the Examiner, and the scope of the present claims.

Example 7 of the Interim Written Description Guidelines, referred to generally by the Examiner, discusses claims in the format:

> An isolated DNA comprising SEQ. ID. NO: 16.

The commentary indicates that the University of California case is controlling, and the written description requirement is not satisfied for a claim like this.

The Guidelines go on, however, in Example 9, to describe the following claim:

> An isolated nucleic acid that specifically hybridizes under highly stringent conditions to the complement of the

> sequence set forth in SEQ. ID. NO: 1, wherein said nucleic acid encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase activity.

The hypothetical states that hybridization conditions are recited (6XSSC, 65°C) – conditions LESS descriptive than what is recited in the current claims) and that only a single sequence is described.

Nonetheless, the written description requirement was deemed satisfied, and the University of California, case was not referred to at all.

At pages 10-12 of the action, the Examiner presents an elaborate argument which, while perhaps interesting, fails to take account of what is claimed. For example, the Examiner notes that "mouse TIF-beta and mouse TIF-alpha respond differently in response to IL-9." This is a red herring. The issue is: (i) do either of their complements of murine TIF-beta and TIF-alpha hybridize, as claimed, and do they stimulate STAT3?" If the answer is yes - as it is - then this issue is irrelevant. As for the Examiner's repeated concern that "critical structural elements" are not recited, the Examiner is directed to the Interim Written Description Guidelines, cited supra, to which the Examiner has, and does direct appellants, at pages 12-13. The Examiner should avail himself of these as well. Further, the Examiner is directed to Enzo Biochem, Inc. v. Gen-Probe, Inc., 63 USPQ2d 1609 (Fed. Cir. 2002), which is much more recent than the cases cited by the Examiner, and which holds:

> "(T)he written description requirement can be met by showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

It is submitted that the Examiner is attempting to establish, as a standard, that the Written Description requirement is not satisfied unless all sequences which are encompassed by a claim are disclosed. This is clearly incorrect standard, unsupported by case law, statute, regulation, or even Examiner Argument. The mere fact that the Examiner says the requirement is not met does not foreclose the issue.

It is submitted that the specification as filed fully and completely describes what is claimed, and the Examiner's rejection should properly be reversed.

VIII. CONCLUSION

It is submitted that the rejection of the claims, alleging that they do not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, is in errork, and should be reversed.

It is further submitted that the rejection of the cliams, alleging that they do not satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, is in error, and should be reversed.

Respectfully submitted,

By _____

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Attachment: Appendix A - Claims

APPENDIX A

Claims Involved in the Appeal of Application Serial No. 09/751,797

Pending Claims 1, 3, 4, 7, 8, 10, 11, 14-16, 18, 19, and 50-52

1. An isolated nucleic acid molecule which encodes a T cell inducible factor which is a protein and which activates STAT3, the complementary sequence of which hybridizes, under stringent conditions defined as 65°C in a 3.5xSSC buffer, 0.02% Ficoll, 0.02% polyvinyl pyrrolidone, 0.02% bovine serum albumin, 25mM NaH2PO4 (pH7), 0.1% SDS, 2mM EDTA, followed by a final wash at 2xSSC room temperature, and 0.1xSSC/0.2% SDS at a temperature up to about 65°C, to at least one of SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 24 or SEQ ID NO: 25.

3. The isolated nucleic acid molecule of claim 1, wherein said molecule is cDNA.

4. The isolated nucleic acid molecule of claim 1, wherein said molecule is genomic DNA.

7. An isolated nucleic acid molecule which encodes the protein encoded by the isolated nucleic acid molecule of claim 1.

8. Expression vector comprising the isolated nucleic acid molecule of claim 1, operably linked to a promoter.

10. Expression vector comprising the isolated nucleic acid molecule of claim 3, operably linked to a promoter.

11. Expression vector comprising the isolated nucleic acid molecule of claim 4, operably linked to a promoter.

14. Recombinant cell comprising the isolated nucleic acid molecule of claim 1.

15. Recombinant cell comprising the isolated nucleic acid molecule of claim 2.

16. Recombinant cell comprising the expression vector of claim 8.

18. Recombinant cell comprising the expression vector of claim 10.

19. Recombinant cell comprising the expression vector of claim 11.

50. The isolated nucleic acid molecule of claim 1, wherein said T cell inducible factor which activates STAT3, has a molecule weight of from about 17 to about 30 kilodaltons, as determined by SDS-PAGE.

51. The isolated nucleic acid molecule of claim 1, which encodes a human T cell derived inducible factor.

52. The isolated nucleic acid molecule of claim 1, which encodes a murine T cell derived inducible factor.